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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,750	07/25/2005	Gregory B Martin	3213/104	6908
7590 Michael L. Goldman Nixon Peabody Clinton Square P O Box 31051 Rochester, NY 14603-1051			EXAMINER NAVARRO, ALBERT MARK	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 04/28/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,750

Applicant(s)

MARTIN ET AL.

Examiner

Mark Navarro

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 103-108 and 110 is/are pending in the application.
- 4a) Of the above claim(s) 105 and 106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 103, 104, 107, 108 and 110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/22/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants amendment filed February 5, 2008 has been received and entered. Claims 1-102 and 109 have been cancelled, and new claim 110 has been added. Consequently, claims 103-108 and 110 are pending in the instant application, of which claims 105-106 and sequences other than the elected SEQ ID NO: 2 have been withdrawn from further consideration as being drawn to a non-elected invention.

All grounds of rejection in the Office Action mailed June 28, 2007 are withdrawn.

The following new grounds of rejection are applied to the amended claims:

Claim Rejections - 35 USC § 112

1. Claims 103-104, and 107-108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of inhibiting programmed cell death in ***plant*** eukaryotes, does not reasonably provide enablement for inhibiting programmed cell death in ***all eukaryotes***. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or

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absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem, Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

First, Lacomme et al (PNAS Vol. 96, pp 7956-7961, 1999) set forth that programmed cell death (PCD) fulfills the same roles, elimination of unwanted cells during development and sacrifice of diseased cells, in both plants and animals. However, "although some similarities exist between the ultrastructural and physiological hallmarks of PCD in animals and plants, evidence for common pathways leading to cell death is **limited**." (Emphasis added, see page 7956). This teaching directly addresses factors 1-2, 4-5, and 7-8.

Finally, Applicants specification provides no guidance as to how to overcome this lack of common pathways between eukaryotic plant cells and eukaryotic mammalian cells, i.e., no working examples of eukaryotic cells other than plant cells. This directly addresses factor 3.

Given the lack of guidance, lack of working examples, and the unpredictable nature of the invention, one of skill in the art would be forced into excessive experimentation in order to practice the instantly claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 103-104, 107-108 and 110 are rejected under 35 U.S.C. 102(b) as being anticipated by Nimchuk et al.

The claims are directed to a method of inhibiting programmed cell death in a eukaryote, said method comprising administering to the eukaryote a bacterial effector protein under conditions effective to inhibit programmed cell death.

Nimchuk et al (Cell Vol. 101, pp 353-363, May 2000) disclose of delivering bacterial effector proteins to eukaryotic plant cells. (See pages 353-354).

It is noted that Nimchuk et al do not characterize the administration of bacterial effector proteins to eukaryotic plant cells as inhibiting programmed cell death, however, given that Nimchuk et al combined eukaryotic plant cells as claimed, with the structurally identical bacterial effector proteins, also as claimed, any property of inhibiting programmed cell death is a necessarily inherent result from combining eukaryotic cells and bacterial effector proteins as claimed.

Furthermore, claims 104 and 107-108 have been included in this rejection for reciting "an amino acid sequence of SEQ ID NO: 2." This allows for short subsequences "of" SEQ ID NO: 2, and given that the bacterial effector protein delivered

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to eukaryotic plant cells by Nimchuk et al shares short "subsequences" in common with SEQ ID NO: 2, the disclosure of Nimchuk et al is deemed to anticipate the claimed invention.

As a suggestion, amendment of the claims to recite "wherein the protein comprises the amino acid sequence of SEQ ID NO: 2" would be sufficient to overcome this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shannon Foley can be reached on (571) 272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
April 22, 2008